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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,507	02/18/2004	Rafail Zubok	532/3X8	2937

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EXAMINER	
CUMBERLEDGE, JERRY L	
ART UNIT	PAPER NUMBER
3733	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,507	ZUBOK ET AL.	
	Examiner	Art Unit	
	JERRY CUMBERLEDGE	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 9-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 9-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments, see pages 9 and 10, filed 04/10/2008 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Gill et al. (US Pub. 2003/0187454 A1) in view of Slotman et al. (US Pat. 5,599,279).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gill et al. (US Pub. 2003/0187454 A1) in view of Slotman et al. (US Pat. 5,599,279) in view of Foley (US Pat. 6,991,654 B2).

Gill discloses a method of replacing at least a portion of an intervertebral disc of an intervertebral disc space of a spinal column, the intervertebral disc space defined at least by respective endplates of first and second adjacent vertebral bones, the method comprising: providing first and second members of an intervertebral disc replacement device as a single unit by way of an intervening insertion plate (Fig. 13, ref. 76) and an insertion handle (Fig. 13, ref. 74), such that the first and second members may be at least one of inserted into and moved within the intervertebral disc space without

substantially changing their orientation with respect to one another (Fig. 17); simultaneously inserting the first and second members of the intervertebral disc replacement device into the intervertebral disc space of the spinal column (Fig. 17)(Fig. 1), the first member including a first articulation surface having a first curved surface and the second member including a second articulation surface having a second curved surface capable of articulating with the first curved surface (Fig. 1a), wherein the first and second articulation surfaces of the respective first and second members of the intervertebral disc replacement device are in substantial registration with one another during their simultaneous insertion into the intervertebral disc space (Fig. 17); and causing first and second vertebral bones to move with respect to each other, such that the first and second members articulate with respect to one another (Fig. 1a).

Gill et al. disclose the claimed invention except for the handle being adapted to detachably engage the insertion plate.

Slotman et al. disclose a surgical device that has a plate portion (Fig. 8, ref. 218) that is detachable to a handle portion (Fig. 8, ref. 214). This enables the handle to be removed from the site of insertion in order to make space for other required instrumentation to be inserted into the surgical site (column 5, lines 32-41).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the handle of Gill et al. to be releaseably connected to the insertion plate of Gill et al. as taught by Slotman et al. in order to enable the handle to be removed from the site of insertion in order to make space for

other required instrumentation to be inserted into the surgical site (column 5, lines 32-41).

Gill et al. in view of Slotman et al. disclose the claimed invention except for inserting at least one intervertebral disc replacement trial into the intervertebral disc space to distract same in a direction along a longitudinal axis of the spinal column; the step of inserting at least one intervertebral disc replacement trial includes using a set of intervertebral disc replacement trials to displace the intervertebral disc space, at least two of the intervertebral disc replacement trials having differing head thicknesses to facilitate distraction of the vertebral bones along the longitudinal axis. Inserting a first of the trials into the intervertebral disc space to facilitate at least some distraction of the first and second vertebral bones; and inserting a second of the trials into the intervertebral disc space to facilitate at least some further distraction of the first and second vertebral bones; where the second trial has a larger head thickness than that of the first trial. Repeating the insertion of further trials having larger and larger head thicknesses to facilitate the distraction of the vertebral bones to a target distance, wherein the target distance is one that substantially maximizes the intervertebral space while substantially preserving an annulus and ligaments associated with the vertebral bones. Levering a handle of the at least one trial to facilitate the distraction of the first and second vertebral bones.

Foley discloses a method of spinal surgery (abstract) that comprises inserting at . least one intervertebral disc replacement trial into the intervertebral disc space to distract same in a direction along a longitudinal axis of the spinal column (column 4,

lines 24-34); the step of inserting at least one intervertebral disc replacement trial includes using a set of intervertebral disc replacement trials to displace the intervertebral disc space, at least two of the intervertebral disc replacement trials having differing head thicknesses to facilitate distraction of the vertebral bones along the longitudinal axis (column 1, lines 21-26). Inserting a first of the trials into the intervertebral disc space to facilitate at least some distraction of the first and second vertebral bones; and inserting a second of the trials into the intervertebral disc space to facilitate at least some further distraction of the first and second vertebral bones, where the second trial has a larger head thickness than that of the first trial (column 1, lines 21-26). Repeating the insertion of further trials having larger and larger head thicknesses to facilitate the distraction of the vertebral bones to a target distance (column 1, lines 21-26), wherein the target distance is one that substantially maximizes the intervertebral space while substantially preserving an annulus and ligaments associated with the vertebral bones (column 16, lines 39-43). Levering a handle of the at least one trial to facilitate the distraction of the first and second vertebral bones (column 1, lines 21-26). This procedure allows the disc space to be properly distracted and allows the surgeon to note the appropriate size of implant that will be used for the surgery (column 4, lines 38-51).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the method of Gill et al. in view of Slotman et al. with steps of using trials to distract the vertebral space as taught by Foley, in order

properly distract the disc space and allow the surgeon to note the appropriate size of implant that will be used for the surgery (column 4, lines 38-51).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gill et al. (US Pub. 2003/0187454 A1) in view of Slotman et al. (US Pat. 5,599,279) in view of Foley (US Pat. 6,991,654 B2) in view of Banick et al. (US Pub. 2003/0093153 A1).

Gill et al. in view of Slotman et al. in view of Foley disclose the claimed invention except for the insertion handle, insertion plate and the first and second members are provided in a sterile assembly in a package for access by a surgeon.

Banick et al. disclose packing various surgical devices in sterile packages (paragraph 0037), in order to ensure that, during a given surgical procedure, a surgeon uses devices that have similar mechanical and biological properties (paragraph 0038).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the method of Gill et al. in view of Slotman et al. in view of Foley to include the step of providing surgical devices in a sterile package for access by the surgeon of Banick et al., in order to ensure that a surgeon uses devices that have similar mechanical and biological properties during a given surgical procedure (paragraph 0038).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gill et al. (US Pub. 2003/0187454 A1) in view of Slotman et al. (US Pat. 5,599,279)

Gill discloses a method of replacing at least a portion of an intervertebral disc of an intervertebral disc space of a spinal column, the intervertebral disc space defined at least by respective endplates of first and second adjacent vertebral bones, the method comprising: maintaining first and second members of an intervertebral disc replacement device as a single assembly (Fig. 17) by way of an insertion plate (Fig. 13, ref. 76), wherein first and second articulation surfaces of the respective first and second members of the intervertebral disc replacement device are in substantial registration with one another during their simultaneous insertion into the intervertebral disc space (Fig. 17)(Fig. 1), the first articulation surface including a first curved surface and the second articulation surface including a second curved surface capable of articulating with the first curved surface (Fig. 1a); using an insertion handle (Fig. 13, ref. 74) in order to manipulate the first and second members as a single unit such that they may be at least one of inserted into and moved within the intervertebral disc space without substantially changing their orientation with respect to one another (Fig. 17); manipulating an actuator of the insertion handle to cause detachment of the insertion plate from the insertion handle (column 5, lines 29-40, since whatever is causing the detachment can be considered to be an actuator); and causing first and second vertebral bones to move with respect to each other, such that the first and second members articulate with respect to one another (Fig. 1a). The method further comprising: removing the insertion plate (Fig. 1). The method further comprising fastening at least one screw retaining element to at least one of the first member of the intervertebral disc replacement device, the second member of the intervertebral disc

replacement device, the first vertebral bone, and the second vertebral bone, wherein the screw retaining element is operable to resist the at least one screw of the first member and the at least one screw of the second member from backing out of the respective vertebral bones.

Gill et al. disclose the claimed invention except for the handle being adapted to detachably engage the insertion plate.

Slotman et al. disclose a surgical device that has a plate portion (Fig. 8, ref. 218) that is detachable to a handle portion (Fig. 8, ref. 214). This enables the handle to be removed from the site of insertion in order to make space for other required instrumentation to be inserted into the surgical site (column 5, lines 32-41).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the handle of Gill et al. to be releaseably connected to the insertion plate of Gill et al. as taught by Slotman et al. in order to enable the handle to be removed from the site of insertion in order to make space for other required instrumentation to be inserted into the surgical site (column 5, lines 32-41).

Claims 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gill et al. (US Pub. 2003/0187454 A1) in view of Slotman et al. (US Pat. 5,599,279) in view of Bray (US Pat. 6,235,034 B1).

Gill et al. in view of Slotman et al. disclose the claimed invention except for the method further comprising steps of using a drill guide, a drill and drilling into vertebral

bone and disengaging the drill guide from the insertion plate.

Bray discloses using a drill guide, a drill and drilling into bone and disengaging the drill guide from the insertion plate (column 3, lines 26-39), in order to ensure that the screw hole is drilled at a proper angle, in order to prevent unwanted widening of a screw hole once the screw is placed in the hole (column 3, lines 39-42).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the method of Gill et al. in view of Slotman et al. to include the use of a drill guide and a drill, and drilling into bone and disengaging the drill guide from the insertion plate as taught by Bray, in order to ensure that the screw hole is drilled at a proper angle, in order to prevent unwanted widening of a screw hole once the screw is placed in the hole (column 3, lines 39-42).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gill et al. (US Pub. 2003/0187454 A1) in view of Slotman et al. (US Pat. 5,599,279) in view of Bray (US Pat. 6,235,034 B1) in view of Lyons et al. (US Pat. 6,413,259 B1).

Gill et al. in view of Slotman et al. in view of Bray disclose the claimed invention except for the method further comprising fastening at least one screw retaining element to at least one of the first member of the intervertebral disc replacement device, the second member of the intervertebral disc replacement device, the first vertebral bone, and the second vertebral bone, wherein the screw retaining element is operable to resist the at least one screw of the first member and the at least one screw of the second member from backing out of the respective vertebral bones.

Lyons et al. disclose screw retaining elements (Fig. 1 ref. 22) that cover different portions of a device (Fig. 1) in order to prevent backing out of screws (column 4, lines 47-49) (column 62-64).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the method of Gill et al. in view of Slotman et al. in view of Bray to include the step of fastening at least one screw retaining element to a device of Lyons et al., in order to prevent backing out of screws (column 4, lines 47-49) (column 4, lines 62-64).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is (571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./
Examiner, Art Unit 3733

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732